UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

KRYSTAL DAINS,

Plaintiff, 5:22-cv-208 (BKS/TWD)

v.

BAYER HEALTHCARE LLC, BAYER ESSURE INC., formerly known as Conceptus, Inc., and BAYER HEALTHCARE PHARMACEUTICALS, INC.,

Defendants.

Appearances:

For Plaintiff:
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Hon. Brenda K. Sannes, Chief United States District Judge:

MEMORANDUM-DECISION AND ORDER

I. INTRODUCTION

Plaintiff Krystal Dains filed suit in New York Supreme Court, Cayuga County, on January 31, 2022, asserting various state-law claims arising out of the implantation of the Essure medical device and subsequent complications. (*See* Dkt. No. 2 (complaint)). Defendant Bayer

HealthCare Pharmaceuticals, Inc. removed the action to this Court by notice of removal on March 4, 2022, based on diversity jurisdiction. (Dkt. No. 1).[1] Defendants Bayer HealthCare LLC; Bayer Essure Inc., formerly known as Conceptus, Inc.; and Bayer HealthCare Pharmaceuticals, Inc. (collectively, "Bayer" or "Defendants") now move to dismiss Plaintiff's complaint under Federal Rule of Civil Procedure 12(b)(6). (Dkt. No. 10).[2] Plaintiff opposed the motion, and Defendants replied. (Dkt. Nos. 27, 28). For the following reasons, Defendants' motion is granted.

II. FACTS[3]

A. The Essure System

Essure is a medical device designed, manufactured, marketed, and sold by Defendants. (Dkt. No. 2, ¶ 12). Essure is a form of permanent birth control which is not intended to be removed. (*Id.* ¶ 13). It consists of two metal "micro-inserts" which are "implanted into the fallopian tubes," expand to fit the contours of the fallopian tubes, and "elicit tissue growth which causes blockage of the tubes" to prevent conception. (*Id.* ¶¶ 10, 14, 16). The inserts are

[1] At the time of removal, none of the other Defendants had appeared or been properly served. Bayer HealthCare Pharmaceuticals, Inc.'s notice of removal sets forth the basis for the Court's diversity jurisdiction. (*See* Dkt. No. 1, ¶¶ 10–24). Plaintiff's complaint also lists Bayer, Inc. and Bayer A.G. as defendants; Plaintiff voluntarily dismissed her claims against those entities on May 3, 2022. (Dkt. No. 20).

[2] The motion to dismiss was filed by Bayer HealthCare Pharmaceuticals, Inc. (*See* Dkt. No. 10). Defendants Bayer Essure Inc. and Bayer HealthCare LLC subsequently sought and received permission to join in Bayer HealthCare Pharmaceuticals, Inc.'s motion. (Dkt. Nos. 23, 26).

[3] The facts are drawn from the complaint. The Court assumes the truth of, and draws reasonable inferences from, the well-pleaded factual allegations. *Faber v. Metro. Life Ins. Co.*, 648 F.3d 98, 104 (2d Cir. 2011). Except as outlined below, the Court declines to take judicial notice of the documents submitted with Defendants' motion to dismiss. (*See* Dkt. No. 10-1, at 9 n.1; Dkt. Nos. 10-4 through 10-13). While Plaintiff does not contest the authenticity of the documents, Defendants do not adequately explain where these documents came from, *cf. Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 60 & n.3 (2d Cir. 2016) (taking judicial notice of an FDA guidance document which was available on the FDA's public website), and consideration of the documents is unnecessary to the Court's resolution of the motion. Similarly, the Court declines to consider the two documents submitted with Plaintiff's opposition. Plaintiff does not argue that either of these documents is incorporated by reference in or integral to the complaint, and she does not explain the relevance of these documents, which appear to be from 2016 and April 2018. (*See* Dkt. No. 27, at 11).

"constructed of a stainless-steel inner coil, a dynamic outer coil made from a nickel and titanium alloy, called Nitinol, and a layer of polyethylene terephthalate, or polyester fibers wound between the inner and outer coils." (*Id.* ¶ 15). An individual must be "trained in Essure" and a "skilled operative hysteroscopist" to implant an Essure device. (*Id.* ¶ 19).

Over a three-month period after implantation of the device, the fibers on the micro-inserts "elicit tissue growth around the coils, which causes bilateral occlusion (blockage) of the fallopian tubes." (*Id.* ¶ 17). This tissue buildup prevents sperm from reaching the ovaries, thereby preventing conception. (*Id.*). After this three-month period, the patient undergoes a "confirmation test" to "determine whether the Essure micro-inserts have created a complete occlusion in each fallopian tube." (*Id.* ¶ 18).

Essure is regulated by the Food and Drug Administration ("FDA") as a Class III medical device.[4] Plaintiff alleges that Bayer Essure Inc. has been "repeatedly cited by regulatory authorities" for violations that impacted patient safety. (*Id.* ¶ 20). For example, in July 2002, the FDA cited Bayer Essure Inc. for "failing to report adverse events identified by patients." (*Id.* ¶ 21). Bayer Essure Inc. was aware that certain failures could occur with the Essure device leading to adverse consequences, including, for example, rusting, traces of lead, degradation of the nitinol and increased toxicity, degradation of the fibers leading to chronic inflammation and possible autoimmune issues, and fracture and breakage. (*Id.* ¶ 22). Plaintiff alleges that Bayer Essure Inc. "concealed thousands of migrations and perforation reports" and never reported the "vast majority of complaints." (*Id.* ¶¶ 23–25; *see also id.* ¶ 71 (alleging that, after a December 2010 FDA inspection, Defendants were cited for deficiencies in "Medical Device Reporting")).

[4] *See* FDA, "ESSURE SYSTEM, Premarket Approval (PMA)," (last updated Oct. 31, 2022), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P020014; *see Apotex*, 823 F.3d at 60 & n.3; *Gale v. Smith & Nephew, Inc.*, 989 F. Supp. 2d 243, 246 n.2 (S.D.N.Y. 2013) (taking judicial notice of fact based on "FDA public records" available on the FDA's website). The parties agree that Essure is a Class III medical device.

B. Plaintiff's Essure Implantation

Plaintiff was implanted with the Essure device in September 2015. (*Id.* ¶ 26). At a "later date," she returned to have the "confirmation test" to determine whether the device had achieved complete occlusion in both fallopian tubes. (*Id.* ¶ 27). It was "discovered that one of the Essure inserts was missing." (*Id.* ¶ 28).

Following this discovery, Plaintiff had "additional surgery and a tubal [ligation] as the result of the migration of the Essure device." (*Id.* ¶ 29). She also had "a series of additional surgeries due to continued pain in her lower left pelvic area, all caused by the defective Essure devices." (*Id.* ¶ 30). Plaintiff alleges that she has "continued to treat . . . up to an[d] including the present with continuous pain[] and heavy bleeding." (*Id.* ¶ 31). On February 18, 2021, Plaintiff underwent another surgery "where it was found that the fallopian tube had connected to the uterus," which will require further surgery. (*Id.*). Plaintiff and her family have had to "adjust their lives to accommodate her ongoing injuries." (*Id.* ¶ 32; *see also id.* ¶ 36 (alleging that she continues to suffer "severe and permanent disabling injuries")). Plaintiff alleges that she and her physician relied on Defendants' marketing of the Essure device and that, had she known the Essure device "would cause the injuries she has suffered, she would not have elected the Essure device for permanent birth control." (*Id.* ¶¶ 33–35).

III. STANDARD OF REVIEW

To survive a motion to dismiss under Rule 12(b)(6) for failure to state a claim, "a complaint must provide 'enough facts to state a claim to relief that is plausible on its face.'" *Mayor & City Council of Balt. v. Citigroup, Inc.*, 709 F.3d 129, 135 (2d Cir. 2013) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). The plaintiff must provide factual allegations sufficient "to raise a right to relief above the speculative level." *Id.* (quoting *Twombly*, 550 U.S. at 555). The Court must accept as true all factual allegations in the complaint and draw all

reasonable inferences in the plaintiff's favor. *See EEOC v. Port Auth.*, 768 F.3d 247, 253 (2d Cir. 2014) (citing *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007)). However, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

IV. ANALYSIS

Plaintiff's complaint lists seventeen separately enumerated causes of action. (Dkt. No. 2, ¶¶ 40–165). Not all of the causes of action are labeled; it is unclear what theory of liability Plaintiff advances in these causes of action, and there is great overlap and duplication among the causes of action. Nevertheless, Plaintiff appears to assert the following claims: product liability claims for design defect, manufacturing defect, and failure to warn, under strict liability and/or negligence theories; negligent training and/or treatment; negligence and negligence per se; breach of implied warranty; breach of express warranty; negligent and intentional misrepresentation; constructive fraud; unfair and deceptive trade practices under New York General Business Law ("GBL"); and unjust enrichment. (*See id.*).[5] Defendants move to dismiss Plaintiff's complaint in its entirety, generally arguing that Plaintiff's claims are preempted by federal law and/or otherwise inadequately pleaded. (*See generally* Dkt. No. 10-1).

A. Applicable Law Regarding Preemption

The FDA regulates medical devices pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA"), as amended by the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 301 et seq. The MDA categorizes medical devices based on the risks they present. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316–17 (2008). Class III devices "present[] a potential

[5] Plaintiff also asserts two causes of action which appear to seek punitive damages. (Dkt. No. 2, ¶¶ 160–65 (sixteenth and seventeenth causes of action)). Because punitive damages are a form of relief, and not an independent cause of action, the Court does not address these causes of action further. *See Doe v. Indyke*, 457 F. Supp. 3d 278, 284 (S.D.N.Y. 2020).

unreasonable risk of illness or injury" and are subject to "premarket approval to provide reasonable assurance of [their] safety and effectiveness." 21 U.S.C. § 360c(a)(1)(C). The premarket approval process is "rigorous," and the FDA will grant such approval "only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Riegel*, 552 U.S. at 317–18 (quoting 21 U.S.C. § 360e(d)); *see id.* at 318 (describing the premarket approval process and the materials considered). As part of this process, the FDA reviews the device's "proposed labeling" and "must determine that the proposed labeling is neither false nor misleading." *Id.* at 318 (citing 21 U.S.C. § 360e(d)(1)(A)). "Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Id.* at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). Approved devices are also subject to continuing reporting requirements, including "the obligation to inform the FDA" of new data concerning the device and the obligation "to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred." *Id.* (citations omitted).

The MDA contains an express preemption clause which provides, with an exception not relevant here, that:

> no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). Thus, any claim arising from a state obligation which imposes a requirement "different from, or in addition to" the requirements of the MDA is expressly

preempted. *Id.*; *see also Riegel*, 552 U.S. at 321, 324 ("Absent other indication, reference to a State's 'requirements' includes its common-law duties.").

The FDCA also provides that all proceedings brought to enforce or restrain violations of the Act "shall be by and in the name of the United States." 21 U.S.C. § 337(a). Section 337(a) thus bars suits by private litigants which challenge noncompliance with federal law. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001) ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." (citing 21 U.S.C. § 337(a))). "In other words, a plaintiff's cause of action is impliedly preempted when it is premised solely on a violation of the FDCA." *Olmstead v. Bayer Corp.*, No. 17-cv-387, 2017 WL 3498696, at *3, 2017 U.S. Dist. LEXIS 129222, at *8 (N.D.N.Y. Aug. 15, 2017); *Glover v. Bausch & Lomb Inc.*, 6 F.4th 229, 237 (2d Cir. 2021) ("To avoid implied preemption . . . claims must be based not on the FDCA, but on 'traditional state tort law which . . . predated the federal enactments in question." (quoting *Buckman*, 531 U.S. at 352–53)).

Together,

> *Riegel* and *Buckman* create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption. The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*).

In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig., 623 F.3d 1200, 1204 (8th Cir. 2010) (citation omitted); *Glover*, 6 F.4th at 237 (same).

Defendants argue that most of Plaintiff's claims are expressly and/or impliedly preempted by the FDCA and MDA. (*See generally* Dkt. No. 10-1). Plaintiff argues in opposition

that the Essure device received a conditional premarket approval ("CPMA") which is "invalid" because Defendants failed to comply with the conditions of approval. (Dkt. No. 27, at 8–12 (citing Dkt. No. 2, ¶¶ 20–25 (alleging, inter alia, that Defendants were cited for "continuous violations that impacted patient safety" and "failing to report adverse events"))). Plaintiff's complaint, however, does not contain any allegations about a conditional premarket approval.[6] Plaintiff also argues that "even if" Defendants have a "valid CPMA," her claims "fall outside" the scope of preemption because they "are grounded in state tort/common law and are based on violations of several federal laws and regulations." (*Id.* at 12).

Thus, the Court proceeds to consider whether Plaintiff's various claims are preempted.

B. Failure-to-Warn Claims

Defendants argue that Plaintiff's claims based on a failure-to-warn theory are expressly and impliedly preempted. (Dkt. No. 10-1, at 13; *see, e.g.*, Dkt. No. 2, ¶¶ 56 (alleging "fail[ure] to warn or instruct" Plaintiff "and/or her health care providers of [possible] extreme complications"), 79–80 (alleging "inadequate warnings" and "inadequate post-marketing warnings or instructions"), 93 ("Defendants failed to adequately and timely warn consumers of this risk.")). Plaintiff responds that, under New York law, a manufacturer has a "duty to warn the medical community and the FDA of all potential dangers which it knows or should know" and that this duty is "parallel" to the requirements under the FDCA and MDA. (Dkt. No. 27, at 15).

Plaintiff's complaint does not allege that the warnings Defendants provided deviated in any way from the language and warnings that the FDA approved for the Essure device.

[6] Moreover, Plaintiff's complaint does not allege that the FDA has withdrawn Essure's premarket approval, and she provides no authority to support her assertion that the "FDCA and MDA are clear that the failure to comply with conditions of approval will invalidate the CPMA." (*See id.* at 8). To the contrary, the FDA has "authority and discretion" to withdraw premarket approval from a device "if there is a violation of conditions." *Olmstead*, 2017 WL 3498696, at *4 n.4, 2017 U.S. Dist. LEXIS 129222, at *9 n.4 (citing *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 815 n.6 (E.D. Pa. 2016)); *see also* 21 C.F.R. § 814.46(a).

Accordingly, Plaintiff has not alleged conduct to underly her failure-to-warn claims "that violates the FDCA," a necessary prerequisite to avoid express preemption. *Cf. Glover*, 6 F.4th at 237; *see also Olmstead*, 2017 WL 3498696, at *4, 2017 U.S. Dist. LEXIS 129222, at *8–9 (finding product liability claims expressly preempted where the plaintiff failed to identify a "parallel federal law" the defendants violated related to her state-law claims). Similarly, to the extent Plaintiff claims that Defendants were required to give any warning or instruction *beyond* the labeling the FDA approved for Essure, such claims are also expressly preempted by the MDA. *English v. Bayer Corp.*, 468 F. Supp. 3d 573, 580 (W.D.N.Y. 2020) (holding that "a claim that defendants were required to issue additional warnings beyond what the FDA prescribed and approved" was "expressly preempted"); *see also In re Medtronic*, 623 F.3d at 1205 (holding that a claim that the defendant was required to give "additional warnings" beyond those approved by the FDA was "precisely the type of state requirement that is 'different from or in addition to' the federal requirement and therefore preempted" (quoting *Riegel*, 552 U.S. at 330)).

Accordingly, the Court grants Defendants' motion to dismiss Plaintiff's failure-to-warn claims.

C. Misrepresentation Claims

Plaintiff's complaint asserts one cause of action for negligent misrepresentation and one for intentional misrepresentation. (Dkt. No. 2, ¶¶ 120–39 (eleventh and twelfth causes of action)).[7] Defendants argue that Plaintiff's misrepresentation claims must be dismissed because (1) Plaintiff "does not allege any deviation from FDA-approved statements" and the claims are

[7] Plaintiff's fourth cause of action asserts that Defendants' "knowing and active concealment and denial of the facts" have "tolled any applicable statutes of limitations." (*See* Dkt. No. 2, ¶¶ 62–65). However, Plaintiff alleges that she "could not reasonably have discovered the unreasonable adverse side effects associated with" and dangerous nature of the Essure device "prior to July 2014." (*Id.* ¶ 63). As this date is more than one year before Plaintiff's implantation with the Essure device in September 2015, the basis for Plaintiff's tolling argument is unclear.

therefore expressly preempted, and (2) Plaintiff does not allege these claims with the particularity required by Federal Rule of Civil Procedure 9(b). (Dkt. No. 10-1, at 14–15, 23). Plaintiff responds that she has alleged the elements of a fraudulent misrepresentation claim under New York law, which imposes "parallel" requirements to those under federal law. (Dkt. No. 27, at 18–19).

The Court concludes that Plaintiff's misrepresentation claims, as alleged, are expressly preempted by the FDCA and MDA. Plaintiff's misrepresentation causes of action allege that Defendants misrepresented and/or failed to adequately warn "about the risks of the Essure device" and that Defendants misled Plaintiff, her physicians, and the public "into believing that the Essure device was safe and effective for use" and about the "risks and benefits" of the device. (*See* Dkt. No. 2, ¶¶ 122, 127, 128, 133). However, as Defendants point out, Plaintiff does not allege any statement or representation that deviated from those approved by the FDA for the device. (Dkt. No. 10-1, at 14 (noting that Plaintiff instead "claims that the approved language was inadequate or untrue")); *see Norman v. Bayer Corp.*, No. 16-cv-253, 2016 WL 4007547, at *5, 2016 U.S. Dist. LEXIS 96993, at *14–15 (D. Conn. July 26, 2016) (noting that the question "is whether any of the alleged misrepresentations by defendant were not approved by the FDA during the PMA process"). Without an allegation of a specific statement which violated FDA-approved statements for the Essure device, Plaintiff's misrepresentation claims are preempted. *See De La Paz v. Bayer Healthcare LLC*, 159 F. Supp. 3d 1085, 1098 (N.D. Cal. 2016) (noting that claims based on statements approved by the FDA are preempted because they "would require a determination that Essure did not conform to the descriptions approved by the FDA"); *Norman*, 2016 WL 4007547, at *5, 2016 U.S. Dist. LEXIS 96993, at *14–15 (finding negligent misrepresentation and breach of express warranty claims preempted to the extent the alleged

misrepresentations were approved by the FDA); *see also Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919, 933 (5th Cir. 2006) (noting that claims based on "marketing that complied with the FDA-approved requirements" could not be maintained because success on such claims "requires a showing that the FDA requirements themselves are deficient").

Furthermore, to the extent Plaintiff's misrepresentation claims are not preempted, they must be dismissed for failure to comply with the requirements of Rule 9(b). Rule 9(b) provides, in relevant part, that "[i]n alleging fraud . . . a party must state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). Pleading fraud with particularity means specifying the "who, what, when, where, and how" of the fraud. *Papworth v. Steel Hector & Davis*, No. 06-cv-1237, 2007 WL 2903944, at *8, 2007 U.S. Dist. LEXIS 72864, at *24 (N.D.N.Y. Sept. 30, 2007). It "requires that the plaintiff (1) detail the statements (or omissions) that the plaintiff contends are fraudulent, (2) identify the speaker, (3) state where and when the statements (or omissions) were made, and (4) explain why the statements (or omissions) are fraudulent." *Eternity Glob. Master Fund Ltd. v. Morgan Guar. Tr. Co. of N.Y.*, 375 F.3d 168, 187 (2d Cir. 2004) (internal quotation marks and citation omitted). That heightened pleading requirement applies to misrepresentation claims, whether the misrepresentation is negligent or intentional. *See Nissan Motor Acceptance Corp. v. Dealmaker Nissan, LLC*, No. 09-cv-196, 2011 WL 94169, at *2, 2011 U.S. Dist. LEXIS 2627, at *8 (N.D.N.Y. Jan. 11, 2011) ("Just as with intentional misrepresentation, negligent misrepresentation must be pled with particularity." (citation omitted)).[8] Plaintiff's vague allegations that Defendants misrepresented the safety of

[8] Although the Second Circuit has not decided whether Rule 9(b) applies to negligent misrepresentation claims, *see Eternity*, 375 F.3d at 188, courts in this Circuit have applied the Rule 9(b) heightened pleading standard. *See Directv, LLC v. Wright*, No. 15-cv-474, 2016 WL 3181170, at *9, 2016 U.S. Dist. LEXIS 72769, at *27 (W.D.N.Y. June 3, 2016) ("[S]ince negligent misrepresentation is a type of fraud, a party pleading negligent misrepresentation is once again subject to a heightened pleading standard under Federal Rule of Civil Procedure 9(b)."); *BNP Paribas Mortg.*

and risks associated with the Essure device fail to satisfy the Rule 9(b) standard, as she offers no details about precise statements that were made, by whom, or when.

Accordingly, the Court grants Defendants' motion to dismiss Plaintiff's misrepresentation claims.

D. Failure-to-Report Claims

The complaint contains allegations that Defendants did not comply with federal regulations requiring them to report certain adverse events to the FDA. (*E.g.*, Dkt. No. 2, ¶¶ 25 (alleging that Defendants "chose not to report the vast majority of complaints"), 79 (alleging "inadequate reporting of the results of the clinical trials and post-marketing clinical experiences with the devices"), 131 ("Defendants did not accurately report the results of adverse events by fraudulently and intentionally withholding . . . the truth regarding Essure device failures for months if not years.")). While the complaint does not contain an expressly denominated "failure-to-report" claim, Defendants argue that any such claim must be dismissed as expressly and impliedly preempted and for failure to plausibly allege causation. (Dkt. No. 10-1, at 15–17). Plaintiff does not expressly respond to this argument, although she argues in her opposition that a manufacturer has a duty under New York law "to warn the medical community and the FDA of all potential dangers which it knows or should know and take appropriate steps." (Dkt. No. 27, at 15).

Courts in this Circuit have disagreed about whether a claim premised on the failure to report adverse events to the FDA is preempted. *See A.F. ex rel. Fogel v. Sorin Grp. USA, Inc.*, 346 F. Supp. 3d 534, 543 (S.D.N.Y. 2018) (noting that "lower courts are split" on whether the

Corp. v. Bank of Am., N.A., 949 F. Supp. 2d 486, 508 (S.D.N.Y. 2013) (collecting district court cases that apply Rule 9(b) to negligent misrepresentation claims).

duty to warn under New York law "may include warning the FDA" (citations omitted)); *see also Glover*, 6 F.4th at 239 (noting that the plaintiffs' claims "can proceed, if at all, only if [state law] provides a cause of action based on a manufacturer's failure to report adverse events to a regulator like the FDA, or to comply with post-approval requirements set by that regulator"). Accordingly, in the absence of more detailed and helpful briefing from the parties on this issue, the Court declines to dismiss Plaintiff's failure-to-report claim as preempted at this time.

However, the Court concludes that any failure-to-report claim must be dismissed because Plaintiff has not plausibly alleged a causal nexus between Defendants' alleged failure to report adverse events and her injury. Plaintiff generally makes only conclusory allegations that she has suffered injuries as a "direct and proximate result of Defendant[s'] wrongful conduct." (*E.g.*, Dkt. No. 2, ¶ 84); *see Faber*, 648 F.3d at 104 (noting that the Court is not "bound to accept conclusory allegations or legal conclusions masquerading as factual conclusions"). Furthermore, the complaint indicates that in July 2002 the FDA cited Defendants for "failing to report adverse events identified by patients." (Dkt. No. 2, ¶ 21). The Court also takes judicial notice of a citizen petition to the FDA dated February 20, 2015, cited to by Defendants, which discusses migration as a risk of the Essure device and Defendants' failure to report such incidents to the FDA. *See* Marcus J. Susen, "Citizen Petition," FDA Docket No. FDA-2015-P-0569 (Feb. 20, 2015), *available at* https://www.regulations.gov/docket/FDA-2015-P-0569/document. Given the FDA's awareness of the alleged deficiencies in Defendants' reporting prior to Plaintiff's implantation, Plaintiff has failed to plausibly allege that any failure to report caused her injuries beginning in 2015 or 2016. *Cf. Norman*, 2016 WL 4007547, at *4, 2016 U.S. Dist. LEXIS 96993, at *12–13 (dismissing "failure to warn the FDA" claim where, inter alia, "the FDA was aware of the[] reporting issues years before plaintiff's device was implanted"); *De La Paz*, 159 F. Supp. 3d at

1097 (finding that the plaintiff "failed to plausibly show that her injuries would have been prevented if Bayer had properly reported the perforation events" where the "FDA became aware of these adverse events more than a year" before the plaintiff's procedure and "informed Bayer of its failure to properly report those events" but did "not require Bayer to take any action to further warn physicians or patients . . . beyond the warnings already in place").

The Court therefore grants Defendants' motion to dismiss Plaintiff's failure-to-report claim.

E. Design Defect Claims

Defendants argue that Plaintiff's design defect claims are expressly preempted. (Dkt. No. 10-1, at 13–14). More specifically, Defendants argue that Plaintiff fails to allege that "Bayer departed from the design for Essure approved by the FDA." (*Id.* (quoting *De La Paz*, 159 F. Supp. 3d at 1095)). Plaintiff does not meaningfully respond to this argument, instead arguing that she has alleged the elements of a state-law design defect claim and that Defendants "violated federal requirements." (Dkt. No. 27, at 14–15).

The Court agrees that Plaintiff's design defect claims are preempted. The complaint contains conclusory allegations of defective design alleging, inter alia, that "the foreseeable risks exceeded the benefits associated with the design" and that "there were other safer design alternatives." (Dkt. No. 2, ¶¶ 75, 82). While Plaintiff also asserts that the device "was designed and/or manufactured in a manner violative of the [FDCA and MDA]," (*id.* ¶ 78), there are no facts alleged supporting this conclusory conclusion. *See Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1178 (C.D. Cal. 2013) (noting that a plaintiff "cannot simply incant the magic words 'Defendant violated FDA regulations' in order to avoid preemption" and that "the vague allegation that Defendants violated federal law is 'insufficient to overcome the preemptive reach of § 360k(a)." (brackets and citations omitted)). Plaintiff has not plausibly alleged facts

suggesting that Defendants deviated from the FDA-approved design for the Essure device, a necessary prerequisite to avoiding express preemption. *Cf. De La Paz*, 159 F. Supp. 3d at 1095 (finding design defect claim preempted where the plaintiff conceded that "she cannot allege that Bayer departed from the design for Essure approved by the FDA"); *Norman*, 2016 WL 4007547, at *3 n.3, 2016 U.S. Dist. LEXIS 96993, at *8 n.3 (finding design defect claim that imposes additional or different requirements from those imposed by the FDA is preempted because the "FDA has approved the design of the Essure"); *Hawkins v. Bayer Corp.*, No. 21-cv-646, 2022 WL 2761379, at *4, 2022 U.S. Dist. LEXIS 126360, at *10–11 (W.D. Tex. Feb. 1, 2022) (recommending dismissal of design defect claim where complaint "does not allege that Bayer strayed from the design for Essure that was approved by the FDA"), *report-recommendation adopted by* 2022 WL 2718541, 2022 U.S. Dist. LEXIS 126306 (W.D. Tex. Feb. 23, 2022).[9] Accordingly, Plaintiff's design defect claims are dismissed.

F. Manufacturing Defect Claims

Defendants argue that Plaintiff's manufacturing defect claims are expressly and implied preempted and inadequately pleaded because Plaintiff "fails to identify violations of specific federal requirements that produced actual defects in *her* specific device and caused her injuries." (Dkt. No. 10-1, at 17–18). The Court agrees. Although Plaintiff alleges that the Essure device was "designed and/or manufactured in a manner violative of" the FDCA and MDA, (Dkt. No. 2, ¶ 89), this allegation is insufficient to plausibly allege that the specific Essure device which was implanted in Plaintiff was manufactured in a way that violated FDA-approved specifications.

[9] To the extent Plaintiff's design defect claim is premised on being implanted with a particular Essure device which deviated from the approved design, such a claim is properly considered a manufacturing defect claim, which the Court discusses below. *See McConologue v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 93, 109–10 (D. Conn. 2014) (finding that the complaint did not allege facts to support a design defect claim where the plaintiff did not allege that the design of the product was defective but rather that the defendant "failed to manufacture the [product] in accordance with its FDA approved design specifications").

There are no facts alleged from which it could be plausibly inferred that there was any defect in the manufacturing process. Her manufacturing defect claims are thus preempted. *Cf. Norman*, 2016 WL 4007547, at *3, 2016 U.S. Dist. LEXIS 96993, at *7–8 ("Plaintiff alleges that there may have been some devices produced with 'non-conforming materials,' but does not allege any plausible reason to think that *her* device came from the non-conforming batch, or that it suffered from any other manufacturing defect."). Indeed, cases finding that a plaintiff's manufacturing defect claim is not preempted involve more detailed factual allegations. *See, e.g.*, *McConologue*, 8 F. Supp. 3d at 105–06 (rejecting preemption argument where the plaintiff alleged, among other details, that his doctor notified him that the batch from which his implanted liner came was manufactured outside the defendant's specifications and that the batch was being recalled); *Gelber v. Stryker Corp.*, 788 F. Supp. 2d 145, 155 (S.D.N.Y. 2011) (finding manufacturing defect claim not preempted where the plaintiff alleged that the product was manufactured with "'manufacturing residuals' that exceeded [defendant's] internal acceptance criteria" and that the device was therefore "adulterated"); *see also Rosen v. St. Jude Med., Inc.*, 41 F. Supp. 3d 170, 181 (N.D.N.Y. 2014) (concluding that a claim alleging that the defendant violated the premarket approval, as long as it is "supported by sufficient factual evidence of the violation and demonstrate[s] a causal connection to the alleged injuries," satisfies *Twombly* and avoids preemption).

Accordingly, the Court grants Defendants' motion to dismiss Plaintiff's manufacturing defect claims.

G. Negligent Training Claim

The complaint alleges that Defendants "failed to properly train agents, staff and/or employees." (Dkt. No. 2, ¶ 51).[10] Defendants argue that any negligent training claim must be dismissed as preempted and inadequately pleaded. (Dkt. No. 10-1, at 19–21). Plaintiff responds that her negligent training claim is "outside the scope of the actual Essure Device" and that Defendants' training requirements are a "contractual obligation" pursuant to the Essure's approval and FDA regulations. (Dkt. No. 27, at 12–14).

The Court concludes that Plaintiff's negligent training claim is preempted. Plaintiff has not alleged that Defendants deviated in any way from the training requirements imposed by the FDA. *See Hill v. Bayer Corp.*, 485 F. Supp. 3d 843, 849–50 (E.D. Mich. 2020) ("Under federal law, when FDA specifies training requirements for Class III medical devices, those requirements must appear in the device's approved labeling." (citing 21 U.S.C. § 360j(e))). As she has not plausibly alleged a violation of the FDCA and MDA, her claim is preempted. And, to the extent Plaintiff alleges that Defendants were obligated to engage in training beyond that required by the FDA, such a claim is expressly preempted as an additional or different requirement from those imposed by the FDA.

Even if a negligent training claim were not preempted, Plaintiff has not adequately pleaded such a claim because she has failed to plausibly plead that any such negligent training caused her injuries. The complaint does not contain any factual allegations, for example, that Defendants were negligent in the training of the doctor who implanted Plaintiff's Essure device, that her doctor's training affected the proper implantation of the device, or that any such error is

[10] Plaintiff also alleges that Defendants were "negligent, careless and reckless with regard to [her] care and treatment." (Dkt. No. 2, ¶ 51). However, there are no factual allegations from which it could be inferred that Defendants had any involvement with Plaintiff's care and treatment specifically. In addition, Plaintiff's opposition references a "negligent entrustment claim." (Dkt. No. 27, at 12–13). However, her complaint, even read liberally, asserts no such claim.

causally related to the alleged injuries she suffers. *Cf. Norman*, 2016 WL 4007547, at *5, 2016 U.S. Dist. LEXIS 96993, at *13–14 (finding that the plaintiff did not allege any facts that could "plausibly suggest that her injuries were the result of the alleged negligent training" where the plaintiff did "not allege that her device was improperly implanted, that it suffered from any defect from how it was handled by any intermediary, or that her injuries were in any other way the result of a mistake by her doctor").

The Court therefore grants Defendants' motion to dismiss Plaintiff's negligent training claim.

H. Warranty Claims

Defendants argue that Plaintiff's breach of warranty claims should be dismissed because they are facially untimely. (Dkt. No. 10-1, at 23–24). Plaintiff does not respond to this argument.

Under New York law, the "usual limitations period for breach-of-warranty claims is four years from the date when tender of delivery is made." *Gelber*, 788 F. Supp. 2d at 166 (quoting N.Y.U.C.C. § 2-725(2)). There is an exception to this general rule for warranties explicitly extending to future performance, *see id.*, but Plaintiff has neither invoked this exception nor alleged in her complaint any such explicit warranty of future performance, *cf. Bausenwein v. Snap-On Inc.*, 529 F. Supp. 3d 31, 42 (N.D.N.Y. 2021) (declining to apply accrual rules regarding future performance where neither party had invoked that exception to the general four-year statute of limitations). Here, Plaintiff was implanted with the Essure device in September 2015, well more than four years before she filed suit in January 2022. Accordingly, the Court grants Defendants' motion to dismiss Plaintiff's breach of warranty claims as time barred.

I. GBL Claim

Plaintiff's complaint asserts a cause of action under New York GBL § 349, alleging that Defendants engaged in unfair and deceptive trade practices. (Dkt. No. 2, ¶¶ 147–54). To state a

claim under GBL § 349, "a plaintiff must allege that a defendant has engaged in (1) consumer-oriented conduct that is (2) materially misleading and that (3) plaintiff suffered injury as a result of the allegedly deceptive act or practice." *Orlander v. Staples, Inc.*, 802 F.3d 289, 300 (2d Cir. 2015) (quoting *Koch v. Acker, Merrall & Condit Co.*, 18 N.Y.3d 940 (2012)). Defendants argue that Plaintiff's GBL claim must be dismissed because, as a matter of law, any alleged deception was not directed at consumers. (Dkt. No. 10-1, at 24). Plaintiff does not respond to this argument.

The Court concludes that Plaintiff has not plausibly alleged a claim under GBL § 349. First, to the extent Plaintiff alleges that Defendants concealed information or deceived the FDA, she has not alleged that such conduct is consumer oriented. *See Gale*, 989 F. Supp. 2d at 250 ("Plaintiff alleges S&N deceived the FDA, but he does not explain how this allegedly improper conduct was 'consumer-oriented.'"). To the extent Plaintiff alleges that Defendants' allegedly deceiving conduct was directed at her, her surgeon, and healthcare professionals, the Court cannot conclude as a matter of law that such conduct was not consumer oriented. *See Himmelstein, McConnell, Gribben, Donoghue & Joseph, LLP v. Matthew Bender & Co., Inc.*, 37 N.Y.3d 169, 177 (2021) (noting that GBL § 349 is "focused on the seller's deception and its subsequent impact on consumer decision-making"). However, Plaintiff has not alleged that Defendants' allegedly deceptive conduct—representing that Essure is "safe and effective"—violated any provision of the FDCA or MDA. Any such claim would therefore be expressly preempted by the MDA. Accordingly, the Court grants Defendants' motion to dismiss Plaintiff's GBL claim.

J. Remaining Claims

In addition to the claims addressed above, Plaintiff's complaint asserts claims for negligence and negligence per se, constructive fraud, and unjust enrichment. (Dkt. No. 2, ¶¶ 97–

107, 140–46, 155–59 (eighth, thirteenth, and fifteenth causes of action)). Defendants' motion does not expressly address these claims. However, Defendants argue that all of Plaintiff's claims should be dismissed for failure to adequately plead causation. (Dkt. No. 10-1, at 21–23 ("Each of Plaintiff's . . . causes of action includes a causation element, yet the Complaint impermissibly relies on conclusory assertions that Bayer's conduct 'caused' Plaintiff's injuries." (internal footnote omitted))). Plaintiff responds that Defendants' argument that Plaintiff has not adequately alleged causation is "belied by plaintiff's allegations in the complaint," because she "has alleged that because of defendants' defective and dangerous Essure device, plaintiff has suffered severe and permanent injuries." (Dkt. No. 27, at 7 n.1).

Plaintiff's negligence and constructive fraud claims entail an element of causation. *Pasternack v. Lab'y Corp. of Am. Holdings*, 27 N.Y.3d 817, 825 (2016) (negligence); *Sanchez v. United States*, No. 13-cv-2536, 2015 WL 667521, at *2, 2015 U.S. Dist. LEXIS 19276, at *5–6 (S.D.N.Y. Feb. 17, 2015) (negligence per se); *Tutor Perini Bldg. Corp. v. N.Y. City. Reg'l Ctr., LLC*, 525 F. Supp. 3d 482, 515–16 (S.D.N.Y. 2021) (constructive fraud). The Court agrees with Defendants that Plaintiff has not plausibly pled that Defendants' alleged negligence or fraud caused her injuries. Plaintiff repeatedly alleges that Defendants' conduct "caused" her injuries or that her injuries are a "direct and proximate result" of that conduct. (*E.g.*, Dkt. No. 2, ¶¶ 46–47, 52–53, 58, 72, 85, 95, 106, 145, 153). However, she fails to allege factual allegations regarding how any tortious or fraudulent conduct actually led to her injuries. Her negligence, negligence per se, and constructive fraud claims must therefore be dismissed. *Cf, e.g.*, *De La Paz*, 159 F. Supp. 3d at 1095 (dismissing claims where the plaintiff "offer[ed] only conclusory allegations that the alleged irregularities caused her injuries" and holding that the "conclusory allegation" that the plaintiff suffered injuries "[a]s a direct and proximate result of one or more of

[defendants'] wrongful acts or omissions" was "not entitled to the presumption of truth on a motion to dismiss" (citing *Iqbal*, 556 U.S. at 681)).[11]

Accordingly, the Court grants Defendants' motion to dismiss.[12]

V. LEAVE TO AMEND

Plaintiff has requested an opportunity to amend the complaint to "address any perceived deficiency" the Court identifies. (Dkt. No. 27, at 20). If Plaintiff seeks leave to file an amended complaint, she must file a letter brief not more than 15 pages long, along with a proposed amended complaint which has proposed insertions and deletions identified, in accord with Local Rule 15.1(a), by November 15, 2022. The Court notes that Plaintiff's response to the motion to dismiss failed to address the applicable preemption law. Any letter brief must detail how the proposed pleading cures the deficiencies the Court has identified and must address applicable preemption law. Defendants may respond to Plaintiff's letter, in a letter brief not more than 15 pages, by November 29, 2022. The Court will determine whether to permit an amendment following this briefing.

VI. CONCLUSION

For these reasons, it is hereby

ORDERED that Defendants' motion to dismiss (Dkt. No. 10) is **GRANTED**; and it is further

[11] Nor is Plaintiff's constructive fraud claim pled with the particularity required by Rule 9(b). *Tutor Perini Bldg. Corp.*, 525 F. Supp. 3d at 516 (subjecting constructive fraud claim to Rule 9(b)).

[12] While an unjust enrichment claim does not necessarily entail an element of causation, such a claim is "not available where it simply duplicates, or replaces, a conventional contract or tort claim." *Cooper v. Anheuser-Busch, LLC*, 553 F. Supp. 3d 83, 115 (S.D.N.Y. 2021) (quoting *Corsello v. Verizon N.Y., Inc.*, 18 N.Y.3d 777, 790–91 (2012)).

ORDERED that if Plaintiff does not file a letter brief proposing amendment by November 15, 2022, the Clerk is directed to dismiss the complaint and close this case without further order.

IT IS SO ORDERED.

Dated: November 1, 2022
Syracuse, New York

Brenda K. Sannes
Chief U.S. District Judge